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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,246

09/12/2006

Mark L. Lawrence

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

01/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,246	Applicant(s) LAWRENCE ET AL.	
	Examiner Mark Navarro	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,13-17,20,26-34 and 46-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-12,18,19,21-25 and 35-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>multiple</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, species *Pasteurella multocida*, claims 1-6, 8-12, 18-19, 21-25, and 35-45 in the reply filed on November 26, 2008 is acknowledged.

Note: claim 6 recites that the bacteria is *Haemophilus*. Accordingly, Applicants response is deemed to have been a simple typographical error and should in fact have recited claims 1-**5**, 8-12, 18-19, 21-25 and 35-45.

Claim Rejections - 35 USC § 112

1. Claims 38 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38 and 43 recite "or other appropriate promoter." One of skill in the art would be unable to determine the metes and bounds of such a limitation. For instance what traits would render the claimed promoter "appropriate?" Likewise, what traits would render the claimed promoter inappropriate? Without a clear definition of the term "other appropriate promoter" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-5, 9-12, 21-25, 35-38 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al in light of Heithoff et al.

The claims are directed to an attenuated strain of a bacteria, said bacteria comprising altered DNA adenine methylase (Dam) activity such that the bacteria are attenuated.

Anderson et al (US Patent Number 4,798,791) disclose of E. coli strain GX3003 that contains a DNA adenine methylase (Dam) mutation. (See Example 1).

Heithoff et al (Science Vol. 284, pp 967-970, May 1999; IDS REF "BY") disclose that bacteria lacking DNA adenine methylase were fully proficient in colonization of mucosal sites but showed severe defects in colonization of deeper tissue sites. Heithoff et al report that Dam inhibitors are likely to have broad antimicrobial action, and Dam

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negative derivatives of these pathogens may serve as live attenuated vaccines. (See abstract).

Accordingly, the Dam mutation disclosed by Anderson et al is deemed to be an attenuating mutation.

3. Claims 1-5, 8-12, 18-19, 21-25, and 35-45 are rejected under 35 U.S.C. 102(a & e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mahan et al.

The claims are directed to an attenuated strain of a bacteria, said bacteria comprising altered DNA adenine methylase (Dam) activity such that the bacteria are attenuated.

Mahan et al (US Publication 2002/0068068) disclose of compositions containing pathogenic bacteria having non-reverting genetic mutations which alter activity of DNA adenine methylase (Dam) resulting in attenuation and methods of using these compositions to elicit an immune response to produce antibodies. (See abstract and claims). Mahan et al specifically set forth that the starting bacteria, to which a mutation of DNA adenine methylase was done, included *Pseudomonas multocida*. (See detailed paragraph 88; and claims 11-12).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
January 27, 2009